

REMARKS

I. Status of the Application

Claims 1-17 are presently pending in the application. Claims 1-9, 11, 13-15 and 17 remain rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., WO 91/01126. Claims 10, 12 and 16 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al.

Applicants thank the Examiner for the telephone interview with Applicants' agent on March 11, 2004 and for the Examiner's voicemail message of March 12, 2004.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Support for the amendments can be found throughout the specification and claims as originally filed. Specifically, support for the amendment to claims 1, 2, 9 and 10 to recite a "flexible implant" can be found in the specification at least at page 11, lines 5-9 where Applicants teach that a plasticizer added to the matrix component produces a flexible material. Claims 1, 2, 9 and 10 were also amended to address formal matters. The amendments presented herein add no new matter.

Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

II. Claims 1-9, 11, 13-15 and 17 Are Novel and Non-Obvious Over Dunn et al.

At page 2, paragraph 1 of the instant Office Action, claims 1-9, 11, 13-15, and 17 remain rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., WO 91/01126. At page 3, paragraph 3 of the instant Office Action, claims 10, 12 and 16 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al. The Examiner is of the opinion that the matrix of

Dunn et al. is identical to that of the instant claims in its components and function and therefore anticipates the claimed invention. The Examiner is further of the opinion that since the result of the method is the same, namely a porous polymeric matrix with active agents useful for guided tissue regeneration, the order in which the components are added would be within the level of skill in the art in order to achieve optimal pore size and release of the agents. The Examiner concludes that the pending claims remain rejected over the cited art.

Applicants respectfully traverse these rejections. As amended, the pending claims are directed to biodegradable implants and methods for making biodegradable implants wherein a plasticizer is dispersed within a rigid matrix to produce a *flexible implant*, and wherein the plasticizer substantially exits from the implant after coming into contact with an organ system or tissue fluids of an organ system. Applicants' claimed implants, due in part to their flexibility, can easily be fashioned into desired shapes (specification, page 4, lines 18-23). The flexibility of Applicants' implants enable them to be shaped to fit a tissue structure in a very precise manner such that a good fit may be achieved upon implantation to allow regenerating tissue to grow in the correct shape with no damage to the surrounding tissue (specification, page 2, lines 8-11).

Due to their rigidity, the claimed implants are able to support tissues during and after implantation. Further, the rigidity allows the implant to retain its shape under the pressure caused by growing tissue and prevents possible external stress from causing movement, which could hamper healing of the tissue (specification, page 2, lines 8-11). Such rigidity allows the implant to support the growth of tissue to the desired shape and size (specification, page 2, lines 14-16). Thus, Applicants' claimed implants have a beneficial balance of flexibility and rigidity that is absent from implants known in the art at the time of filing (specification page 2, lines 7-8).

In the instant Office Action at page 5, the Examiner acknowledges that Dunn et al. does not refer to a matrix as being “rigid.” However, the Examiner believes that based on the dictionary definition of “rigid,” the liquid or semi-liquid injectable materials of Dunn et al. can be “rigid” insofar as they do not bend. Applicants respectfully traverse the Examiner’s interpretation of “rigid” as including liquid or semi-liquid materials as Applicants believe one of skill in the art would not understand rigid as describing a characteristic of liquid or semi-liquid materials, but would rather describe a characteristic of solid materials.

To relieve the Examiner’s concerns, Applicants have clarified that the claimed implants comprising the matrix and the plasticizer are flexible. The implant matrix of Dunn et al. is a liquid or a semi-liquid and so is not flexible. Dunn et al. neither teaches nor suggests a flexible implant or the importance of an implant having flexible properties. Dunn et al. instead teaches liquid implants that cure to form solid implants (page 5, lines 11-16). The implants of Dunn et al. are either injected into the body as a liquid (page 11, lines 2-5) or set outside the body so they may be shaped or molded prior to implantation (page 6, lines 22-28). Nowhere does the reference teach flexible implants or that a flexible implant can achieve a beneficial fit during implantation as is can be accomplished using Applicants’ claimed flexible implants.

As Dunn et al. fails to teach or suggest Applicants’ claimed invention, Applicants request that the rejections of claims 1-9, 11, 13-15 and 17 under 35 U.S.C. §102(b) and claims 10, 12 and 16 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

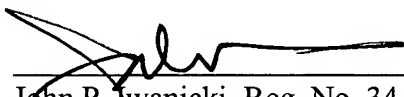
III. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

Date: _____

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